DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 23, 2015

Speed Dental Co., Ltd.
c/o Ho Dong Yang
CEO
Onbix Corporation
#821 Samil Plaza, 837-26 Yeuksam-dong
Gangnam-gu, Seoul 135-768
KOREA

Re: K150141
Trade/Device Name: Orthodontics Bracket
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: July 21, 2015
Received: July 27, 2015

Dear Ho Dong Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150141

Device Name
Trade name: Orthodontics Bracket

Indications for Use *(Describe)*
This device is intended for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single use only

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.

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Date Summary Prepared: OCT 21, 2015

Device Information:

Trade Name(s):	Orthodonics Bracket
Classification Name:	bracket, orthodontic, ceramic
Panel:	dental
Product code:	NJM

Predicate Device Information:
K073045 / Sapphire Ceramic Bracket

Device Description:
The brackets are bonded to teeth to apply pressure to the tooth, transmitted through a flexible orthodontics wire, to alter the tooth position. The ceramic bracket is produced using Al203, translucent polycrystalline aluminum ox-ide(99.99%). The brackets are bonded to the teeth with commercially available materials and linked together by "arch wire" that applies steady, gentle pressure to produce desired tooth movement.

Indications for Use:
This device is intended for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single use only.

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

* indications for use
* technological characteristics
* performance properties

Summary of the technological characteristics compared to the predicate device

new device is substantially equivalent to the predicate device in its technological characteristics stated in the comparison table provided below

Comparison table is as follows

	Orthodontics Bracket	Sapphire Ceramic Bracket
Manufacturer	Speed Dental Co., Ltd.	Ortho Technology Inc
510(k) Number	K150141	K073045
Indications for use	This device is intended for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single use only	Sapphire Ceramic Bracket is intended for use in orthodontic treatments. The brackets are affixed to teeth so that pressure can be exerted on the teeth.
Material	Aluminum Oxide	Aluminum Oxide
Biocompatibility	Meets the applicable requirement of ISO 10993	Meets the applicable requirement of ISO 10993
Maxillary In-out(mm)	1.04 – 1.19	0.53 - 0.89
Maxillary Torque(mm)	-7 to +12	-7 to +17
Maxillary Angulation	0 - 10	0.51 – 10
Slot	0.022″	0.022″
Transparency	Half-transparency	Half-transparency
Colour	White, same as tooth colour	White, same as tooth colour
Indication system	Coloured-dot	dot
Design parts	Hook, Slot, Round home, base and marking	Hook, Slot, Round home, base and marking
Intended use	This medical device is a bracket to be attached to	Sapphire Ceramic Bracket is intended for use in orthodontic treatment. The brackets are affixed

	teeth for orthodontic purpose and it is made of ceramic material.	to teeth so that pressure can be exerted on the teeth.

Differences between the proposed and predicate devices are not expected to affect the overall performance of the device. These differences include slight variations in design such as maxillary angulation and torque. While the ranges are not identical, they are still within the range of what is typically observed for orthodontic brackets.

Non-Clinical Study performance

In addition to testing to determine maxillary torque, the orthodontic bracket was found to be in compliance with biocompatibility, biocompatibility study has been applied to the new device in accordance with the following standard

ISO 10993 Biological evaluation of medical devices
- Part 1 – Evaluation and testing in the risk management process
- Part 5 – Tests for in vitro cytotoxicity
- Part 10 – Tests for irritation and delayed-type hypersensitivity

Conclusion

The Orthodontics Bracket has the same device characteristics as the predicate device, Based on the information provided in this summary we conclude that Orthodontics Bracket is substantially equivalent to the predicate device K073045.